WatchPAT™200

Operation Manual

Itamar Medical REF OM2196330

Caution: **Federal (U.S.) law restricts this device to sale by, or on the order of, a physician. Not for pediatric use**.

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This product and/or method of use, is covered by one or more of the following US patents: 6319205, 6322515, 6461305, 6488633, 6916289, 6939304, 7374540, as well as any pending US patent applications and corresponding patents and/or applications filed in other countries.

ISO 9001:2008 and EN ISO 13485:2012
See appendix D for contact information of the regulatory authorized representative

Record of Editions

Edition	Date	Description	Chapter	Pages	Resp.
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Note: Latest version of the WatchPAT™ system Operation Manual is available at:
http://www.itamar-medical.com/Support/Downloads.html

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1 GENERAL INFORMATION

This manual is part of the WatchPAT™200 system.

1.1 Intended use / Indications for Use

The WatchPAT™200 (WP200) device is a non-invasive home care device for use with patients suspected to have sleep related breathing disorders. The WP200 is a diagnostic aid for the detection of sleep related breathing disorders, sleep staging (Rapid Eye Movement (REM) Sleep, Light Sleep, Deep Sleep and Wake), snoring level and body position. The WP200 generates a peripheral arterial tonometry ("PAT®") Respiratory Disturbance Index ("PRDI"), Apnea-Hypopnea index ("PAHI"), PAT sleep staging identification (PSTAGES) and optional snoring level and body position discrete states from an external integrated snoring and body position (SBP) sensor. The WP200's PSTAGES and SBP provide supplemental information to its PRDI/PAHI. The WP200's PSTAGES and SBP are not intended to be used as the sole or primary basis for diagnosing any sleep related breathing disorder, prescribing treatment, or determining whether additional diagnostic assessment is warranted.

The WatchPAT™200 device is not indicated for children less than 17 years old.

1.2 Restrictions for Use

1. The WP200 should be used only in accordance with physician's instructions. For exclusion criteria see Section 1.3.
2. Only qualified medical personnel may authorize the use of the WP200.
3. Qualified medical personnel must instruct the patients how to attach and use the WP200 prior to use.
4. In the event of equipment malfunction all repairs should be executed by authorized Itamar Medical Ltd. personnel or licensed service agents.
5. The eligibility of a patient for a PAT® study is entirely at the discretion of a physician, and is generally based upon the patient's medical status.
6. The WP200 system in whole, or in part, may not be modified in any way.
7. The WP200 is used as an aid for diagnostic purposes only, and should not be used for monitoring.
8. Only suitably trained and qualified personnel should be authorized to prepare the WP200 equipment prior to use.
9. The WP200 Operation Manual should be carefully studied by the authorized operators, and kept where it is easily accessible. Periodic review of the Manual is recommended.
10. Itamar Medical Ltd. makes no representation whatsoever, that the act of reading the Manual renders the reader qualified to operate, test or calibrate the system.
11. The tracings and calculations provided by the WP200 system are intended as tools for the competent diagnostician. They are explicitly not to be regarded as a sole incontrovertible basis for clinical diagnosis.

12. In the event that the system does not operate properly, or if it fails to respond to the controls in the manner described in this Manual, the operator should refer to the Troubleshooting section. If necessary, contact our service office to report the incident, and to receive further instructions.
13. The step by step instructions for the patient should be carefully followed when attaching the unit to the patient.
14. The WP200 device is not indicated for children less than 17 years old.

1.3 Exclusion Criteria

The WatchPAT™200 device should not be used in the following cases:

1. Use of one of the following medications: alpha blockers, short acting nitrates (less than 3 hours before the study).
2. Permanent pacemaker: atrial pacing or VVI without sinus rhythm.
3. Sustained* non-sinus cardiac arrhythmias.
   ** In cases of patient having accumulative time of regular R-R intervals of less than 1.5 hours, the WP200 will not have sufficient valid PAT® signal as required to generate a sleep report.*

1.4 Data Generated by the WatchPAT™200 Device

The WatchPAT™200 device generates a PAT® respiratory disturbance index ("PRDI") and its derivative, the PAT® Apnea-Hypopnea Index ("PAHI") and PAT® sleep staging identification ("PSTAGES"). The PAHI and PRDI are estimates of conventional RDI and AHI values and REM, DEEP SLEEP, LIGHT SLEEP, and WAKE stages identification that are produced by polysomnography ("PSG"). The WatchPAT™200 device also generates optional acoustic decibel detector used for snoring level and body position discrete states from an external integrated snoring and body position (SBP) sensor.

1.5 Equipment Classification

The WatchPAT™200 device is a Class IIa medical device under MDD 93/42/EEC, 2007/47/EC Annex IX rule 10.

1.6 Quality Assurance System: ISO 9001 & ISO 13485

The Itamar Medical WatchPAT™200 device is compliant to the following standards.

	STANDARD	#
1.	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	IEC 60601-1
2.	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	IEC 60601-1-2
3.	Medical Device Software – Software Life Cycle Processes	IEC 62304
4.	Medical electrical equipment - Part 1-4: General requirements for safety – Collateral Standard: Programmable electrical medical systems	IEC 60601-1-4
5.	Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	IEC 60601-1-11
6.	Degrees of protection provided by enclosures (IP Code) – IP22	IEC 60529
7.	Quality management systems - requirements	ISO 9001:2008
8.	Medical devices. Quality management systems. Requirements for regulatory purposes	EN ISO 13485:2012
9.	Medical devices - Quality management systems - Requirements for regulatory purposes (Health Canada)	CAN/CSA-ISO 13485 :2003
10.	Medical devices. Application of risk management to medical devices	ISO 14971
11.	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements	ISO 15223-1
12.	Symbols for use in the labelling of medical devices	EN 980
13.	Graphical symbols for electrical equipment in medical practice	IEC TR 60878
14.	Graphical symbols - Safety colours and safety signs -- Registered safety signs; refer to instruction manual/ booklet	ISO 7010-M002
15.	Information supplied by the manufacture with medical devices	EN 1041
16.	Biological evaluation of medical devices - Part 1: Evaluation and testing	ISO 10993-1
17.	Medical devices - Application of usability engineering to medical devices	BS EN 62366

18.	Medical Device Directive	MDD 93/42 EEC MDD 2007/47/EC
19.	FDA Quality Systems Regulation (QSR)	21 CFR part 820
20.	UL standard for safety	UL 60601-1
21.	CSA Standard for safety	CSA 22.2 No.601.1
22.	Canadian Medical Devices Regulation	SOR/98-282

1.7 CE and CSA Compliance

The product complies with the CE mark according to MDD (Medical Device Directive) and related standards.

The unit is marked with the CE logo.

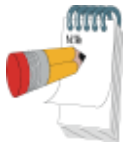
The product is certified by CSA.

1.8 Conventions Used in this Manual

Note: Throughout this document, the references WatchPAT™ and WP200 device are used to refer to the WatchPAT™200 device.

	Warnings are used to identify conditions or actions, which - if the instructions are ignored - may violate patient safety, or cause damage/malfunction to the system, resulting in non-recoverable loss of data. **Les avertissements** sont utilisés pour identifier les conditions ou les actions qui- si elles sont ignorées- peuvent porter atteinte à la sécurité des patients ou causer des dommages au système et résulter à une perte irréversible des données.

	Cautions are used to identify conditions or actions, which could cause interference with data acquisition and/or impair study results. **Les précautions** sont utilisées affin d'identifier les conditions ou les actions qui peuvent interférer avec le ramassage de données et provoquer des résultats équivoque.

	**Notes** are used to identify an explanation, or to provide additional information for purposes of clarification. **Les notes** sont utilisées pour identifier les explications et pour donner des informations supplémentaires dans le but de clarifier.

1.9 Warnings, Cautions and Notes

The WatchPAT™200 device is internally powered from a 4.2 V battery.
The WatchPAT™200 device is portable with continuous operation.
The WatchPAT™200 device uses BF patient applied parts.
The WatchPAT™200 device uses UL listed power supply (USA & Canada only).
The power supply is used in a non-patient environment only.
The WatchPAT™200 device should only be transported in its original case.
There are no serviceable parts inside the WatchPAT™200 device.
Do not use WatchPAT™200 device for non-indicated purpose, such as oximetry for ICU patient monitoring or alarm device.
Environmental conditions during transportation & storage: See Specifications section.
Environmental conditions during operation: See Specifications section.

Sleep professionals (other than patients) using the WatchPAT™200 system should read the Operation Manual.

1.10 Safety Precautions

WARNINGS

Use only the AC adapter provided (5V DC, 5W maximum capacity power supply). Only authorized personnel may charge the WatchPAT™200. Failure to heed this warning may cause permanent damage to the equipment.

Do not let the unit get wet.

Avoid placing food or water on any part of the system.

In the event of fire use only fire extinguishers approved for use on electrical fires.

Handle unit with care. This unit is sensitive to extreme movements and to falling.

Do not attempt to connect or disconnect any part of the unit.

Do not try to introduce any foreign object into the unit.

The WatchPAT™200 MUST be charged ONLY after being removed from the patient!

The WatchPAT™200 MUST be removed from the patient BEFORE connecting it to a PC!

The Adult Flex Pulse Oximetry Sensor may cause skin sensitivity to the patient. Discontinue use of the NONIN double-backed adhesive tape strips if the patient exhibits allergic reactions to the adhesive material.

AVERTISSEMENTS

Utiliser seulement un 5V DC, 5W alimentation d'énergie. Seul les techniciens autorisés peuvent charger la montre PAT. Ignorer cet avertissement peut causer des dommages irréparables a l'équipement. Ne pas mouiller l'unité. L'unité est sensible au mouvement extrême est à la chute. L'utiliser avec précaution. Ne pas essayer de brancher ou débrancher une des parties de l'unité.

Ne pas introduire un objet étranger a l'intérieur de l'unité.

Le système WatchPAT™200 **doit** être rechargé **uniquement** après avoir été retiré de la main du patient.

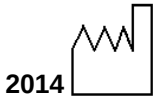
Il est impératif de retirer le système WatchPAT™200 de la main du patient **avant** de le relier a l'ordinateur pour faire fonctioner les programmes.

L'Oxymètre pur adulte '' Flex Pulse'' peut produire des sensibilités dermatologique aux patients.

1.11 Environmental protection

The WatchPAT™200 device including its accessories shall be treated in accordance with the local laws and regulations for proper waste treatment.

1.12 Symbols Used On the Product Labels

	Follow instructions for use
	Type BF applied part
	The product is certified by CSA
	The product complies with the CE mark according to MDD (Medical Device Directive) and related standards. The product is marked with the CE logo.
	Date of manufacture
	Battery Operating Voltage
	Single use, do not re-use
	Temperature limit
	Use-by date
	Medical device Manufacturer
	Catalogue Number
	Serial Number
IP22	Ingress protection

1.13 WatchPAT™200 Device Labels

Located on WatchPAT™200 device

Located on WatchPAT™200 device

Located on Nonin module

1.14 FDA information

The WatchPAT200 is cleared by the FDA under K102567, trade name Watch-PAT 200S-3 (WP200S-3) and under K081982, trade name Watch-PAT 200S-2 (WP200S-2).

2 OVERVIEW

Obstructive sleep apnea syndrome (OSAS) is considered a major public health problem. The prevalence of the syndrome is estimated at 2% to 5% in the adult population. It is characterized by recurrent events of complete or partial obstruction of the upper airways during sleep, often leading to hypoxemia, and/or arousals associated with sympathetic nervous system activation. The diagnosis and assessment of the sleep apnea patient is based on the Respiratory Disturbance Index (RDI), the number of Apneas, Hypopneas and Respiratory Effort Related Arousals (RERA) per hour of sleep, along with sleep architecture. The common consequences of this sleep disruption are daytime sleepiness, poor daytime performance and increased vulnerability to accidents. Cardiovascular complications such as systemic/pulmonary hypertension, ischemic heart disease and arrhythmias are the major sequel of OSAS in the adult population.

The WatchPAT™ device is worn on the wrist and is utilizing a plethysmographic based finger–mounted probe, to measure the PAT® (Peripheral Arterial Tone) signal. The PAT® signal is a measurement of the pulsatile volume changes in the fingertip arteries which reflects the relative state of the arterial vasomotor activity, and thus indirectly the level of sympathetic activation. Peripheral arterial vasoconstriction, which mirrors sympathetic activation, is shown as attenuation in the PAT® signal amplitude. The PAT® signal is recorded continuously and stored on an embedded micro SD card, together with data from a built-in pulse-oximetry sensor (mounted on an adjacent finger) and an actigraph (embedded in the WatchPAT™200 device). Following the sleep study, the recordings are automatically downloaded and analyzed in an offline procedure using the proprietary zzzPAT software.

The zzzPAT algorithms use the four WatchPAT™ channels (PAT®, Pulse Rate, Oxygen saturation and actigraphy) for the detection of sleep related breathing disorders and sleep staging (Rapid Eye Movement (REM), Light Sleep, Deep Sleep and Wake). The zzzPAT uses WatchPAT™ device snoring and body position channels (SBP) to generate snoring level and body position discrete states. The use of SBP is optional and according to physician preference.

The software issues comprehensive reports of the study, with statistics and graphic presentation of the results. The whole night data can be viewed and the automatically detected events can be revised manually.

2.1 System Description

The WatchPAT™ system is comprised of the following items:

- WatchPAT™ system that includes:
  - Embedded actigraph
  - Embedded pulse oximeter
  - Embedded CPU and electrical circuit card
  - Embedded micro SD card drive
  - Rechargeable Lithium Ion Battery
  - LCD display
- PAT® probe
- PAT® probe connection cable
- Pulse oximeter sensor – with single use adhesive pads
- Wrist Strap
- Snore and Body Position sensor – optional
- Cable for Tamper-Proof Bracelet - optional
- AC adapter
- USB cable
- Step-by-Step Reference Guide (to be used in conjunction with Section 7)
- Quick Reference Cards (to be used in conjunction with Section 8)
- Carrying case

Figure 1 – Packed Device

Figure 2 – WatchPAT™ Device with Sensors

An additional item required for the operation of the system is the zzzPAT kit. zzzPAT is a proprietary PC software for initializing the study, retrieving, analyzing and displaying the data. For more information, refer to the zzzPAT Operation Manual.

2.2 User Interaction with the WatchPAT™ Device Keys

The WatchPAT™ device has the following keys (see Figure 3):

- Central On/Enter key to power on the WatchPAT™ device (the only key visible to the patient)
- Outer ring containing four keys (left, right, up, down) that may be used by the Operator for entering the diagnostic mode and navigating through the diagnostic menu. These keys are hidden from the patient.

Figure 3 – The Buttons and Display

LCD Display

The display is used for reading status and error messages. The display is divided to three sections: Title, Info and Status.

- Title (first line): Current operational mode and time
    - PATIENT mode while recording night study
    - DIAGNOSTIC mode while testing device
    - PC HOST while connecting to PC
    - CHARGER mode while connecting to AC adapter
- Info (2^{nd}-5^{th} line): Specific information depending on operational mode
- Status (last line): Message indicating device status depending on operational mode

Service Ports and Peripherals

The WatchPAT™ device has 4 ports that are used either for sensor connections or for servicing and charging (see Figure 4).

- The oximetry module port is used for connecting the oximetry module. The oximetry module has 2 additional ports: one for connecting the oximetry sensor and one for connecting the bracelet (see Figure 5).
- The PAT® probe port is used for connecting the PAT® probe
- A port for connecting the optional Snore & Body Position sensor
- The USB port is used for charging or connecting to the PC

PAT® probe port
Port for optional Snore & Body Position sensor
Oximetry module port
USB port for charging and communication

Figure 4 – Service Ports and Peripherals

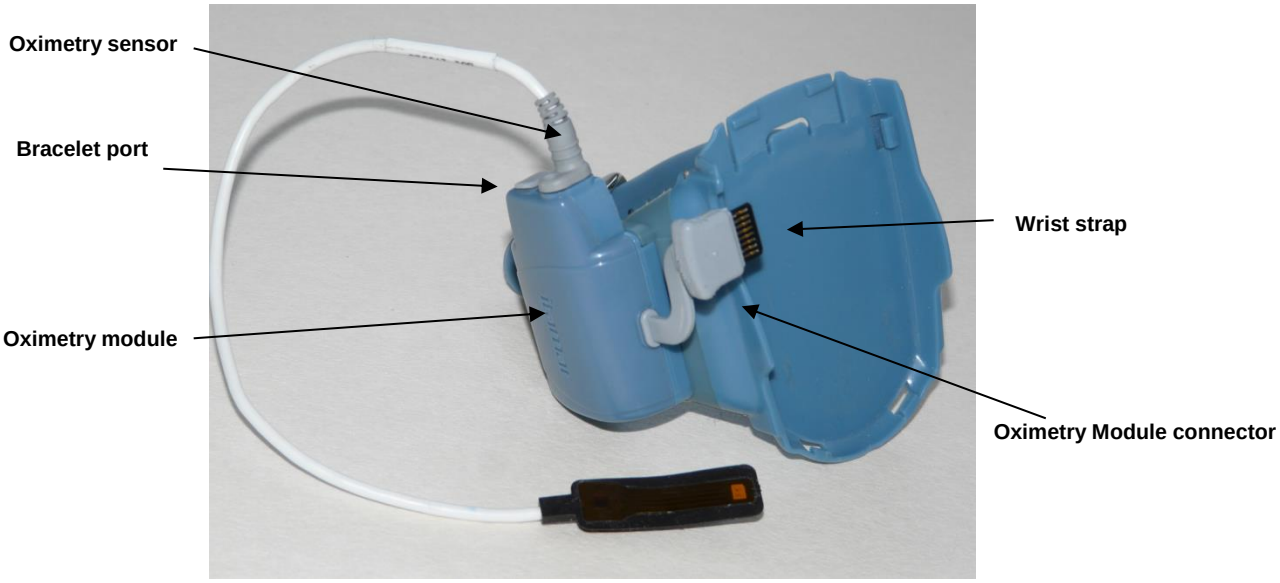


Figure 5 – WatchPAT™ Wrist with Oximetry Module

2.3 WatchPAT™ Device Function

The WatchPAT™ device records the following channels:

- PAT® Signal
- Oxygen saturation
- Actigraphy (movement)
- Acoustic decibel detector for Snoring evaluation (optional)
- Body Position (optional)

The overnight sleep study data is stored on an embedded micro SD card in the WatchPAT™ device. After the study is recorded, the data is downloaded from the WatchPAT™ device through the USB cable using the zzzPAT software. The zzzPAT software, utilizing automatic algorithms, detects respiratory and other events that occurred during sleep as well as periods of REM, deep sleep, light sleep and wakefulness. The pulse rate signal is derived from the PAT® signal and used in the automatic analysis. The software issues comprehensive detailed reports of the study. The whole night data can be viewed on the PC screen and the automatically detected events can be revised manually.

An optional tamper-proof patient identification function is available using a custom bracelet whose presence during the night verifies that the identified patient is indeed the one sleeping with the device (see section Tamper-Proof Testing with WatchPAT™ Device).

The patient normally sleeps only one night with the WatchPAT™ device unless an optional multi-night option is selected which enables an up to 3 nights study with the same device (see Multi-night study section).

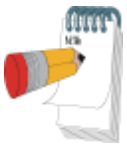
2.4 Built-In Self-Diagnostic Procedures

2.4.1 Operator Tests

The WatchPAT™ device contains a comprehensive built-in self-diagnostic procedure. This procedure is available to the operator and hidden from the patient. The procedure can be accessed it the UP and DOWN keys (see Figure 3) are pressed simultaneously after the device is powered ON (during the first 30 seconds only after the device is powered ON). The procedure performs the following tests:

- Device Test – tests the WatchPAT™ device for errors before performing a night study (make sure all probes are connected before initiating this test)
- Oximetry Sensor Test – verifies oximetry sensor is connected and shows average saturation

The Device test is the default test. Once the device test has passed you should also run the oximetry sensor test.



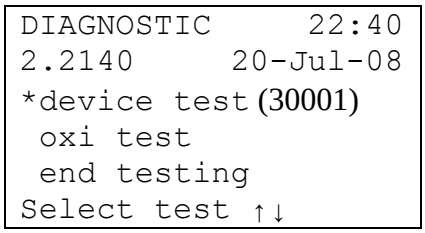
Note

In all times, the current time is shown in the upper right hand corner of the LCD display.

To run the self-diagnostic procedure:

- Press the ENTER button (Center key) for 2 seconds till the Itamar medical logo appears on the LCD screen
- Immediately press the **UP + DOWN** keys (see Figure 3) simultaneously for 1 second

The following screen will be displayed:

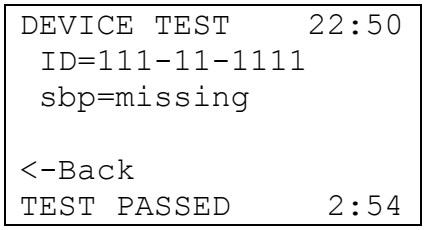


- First line displays title and current time
- Second line displays current embedded S/W version (2.2139) and current date
- Third line displays option for running device test (serial number of device in parenthesis)
- Fourth line displays option for running oximetry sensor test
- Fifth line indicates option for end testing (turn device off). If no test is selected within 3 minutes the WatchPAT™ device will automatically shut down
- The Up & Down keys (↑↓) navigate between the lines.
- An asterisk will indicate current selection. When moving the ↑↓ keys, the asterisk will move to indicate the current selection. Press the central Enter key to make the desired selection.

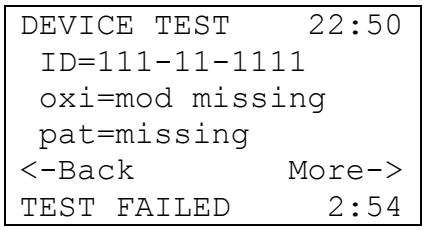
It is recommended that you perform the Device and OXI test every time you prepare the WatchPAT™ device for a night study.

2.4.2 Device Test

At the completion of the device test, a **TEST PASSED** indicates that the device is ready for the night study.



At the completion of the device test, a **TEST FAILED** indicates a problem that should be taken care of before the device is released for a night study.



The following are the possible error, warning or information messages:

- File error: not loaded, missing – the study file was not loaded or somehow the file was deleted
- File error: used x/3 x=1..3 – only when multi-night option is selected
- Battery error: low – needs charging
- Probe error: used, missing, bad – connect an unused probe
- Oximetry error: module missing - connect oximetry module
- Hardware (H/W) error: error code - contact customer support
- SBP (Snore and Body Position sensor) warning: sensor missing – does not affect PASSED status
- RTC (Real Time Clock) warning: faulty – indicates problem with internal clock but does not affect PASSED status
- Bracelet error: missing – the study file was chosen with the bracelet option but the bracelet is not connected during the device test
- Information messages:
    - multi-night=on - when a multi night study is required
    - bracelet=on - when a study with tamper-proof patient identification bracelet is required

`More->` indicates that there are more error/warning messages and will be displayed if the Right (`->`) button is pressed.
`<-Back` will move to the previous screen if the Left (`<-`) button is pressed.

2.4.3 Oximetry Test

For the oximetry test make sure the sensor is attached to the finger. At the end of the test the saturation and/or any error message will be displayed:

```
OXI TEST        22:50
SaO2=98%

Attach to finger
<-Back
Testing…
```

```
OXI TEST        22:50
SaO2=N/A
oxi=mod missing
Attach to finger
<-Back
Testing…
```

The possible oximetry error messages are:

- Oximetry error: module or sensor missing - connect oximetry module and sensor.
- SaO2= Not Available (N/A) - attach sensor to finger.

The blood saturation is continuously updated, therefore wait approximately for one minute for the saturation to stabilize when testing.
`<-Back` will move to the previous screen if the Left (<-) button is pressed.

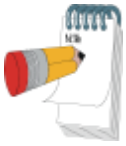
2.4.4 Patient Test

When the patient turns on the WatchPAT™ device by pushing the On/Enter key (center button) for about 2 seconds a self-diagnostic test is automatically performed and the following screen is displayed:

```
PATIENT         22:51



Please wait
Testing…
```

If the WatchPAT™ device passes this self-diagnostic test, the following screen will be displayed:

```
PATIENT         22:51

GOOD NIGHT!!!

Time elapsed=9:50
Recording…
```

	**Note** During recording the LCD display turns off to conserve battery life. Any key pressed during Recording will turn on the LCD for 30 seconds.

If the WatchPAT™ device fails this self-diagnostic test, the following screen will be displayed:

```
PATIENT          22:51
Error=xxxx
Device S/N=xxxxx

Call Help Desk
TEST ABORTED
```

- The error message will be displayed for 1 minute and then the WatchPAT™ device will shut off.
- If this is a study with the tamper-proof bracelet and the wrong bracelet is connected the "wrong bracelet" error message appears.
- If this is study with the tamper-proof bracelet and the bracelet is not connected the "connect bracelet" error message appears in order to remind the patient to connect the bracelet.

The following are the possible error/warning messages:

xxx1 - Battery low

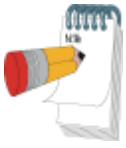
xxx2 – Nonin module/sensor disconnected

xx2x – PAT® probe error (used probe)

xx4x – File error (no new file)

xx8x – PAT® probe error (bad probe)

x4xx – SBP (Snore and Body Position sensor) missing warning

	**Note** The "x" stands for 0-F value (Hexadecimal code) Error codes are additive, i.e. both PAT® probe and File errors will produce error code xx6x.

3 PREPARATION FOR SLEEP STUDY

3.1 Charging the Battery

The battery must be charged every time the WatchPAT™ device is prepared for use. The battery may be charged using the AC adapter provided.

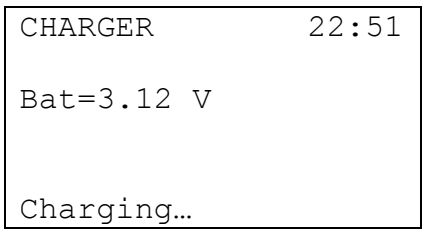
To charge the WatchPAT™ device:

1. Disconnect the Oximetry module by disconnecting the Oximetry module connector.
2. Gently slide the WatchPAT™ device out of the wrist strap until a click is heard and the USB port is exposed. Be careful not to damage the oximetry module connector and cable.
3. Connect the USB port of the WatchPAT™ device to the AC adapter provided (see Figure 6).

	Warning For charging use only an AC adapter having a 5V DC output, with 5W minimum capacity. Using any other AC adapter may cause permanent damage to the WatchPAT™ and may jeopardize the operator.

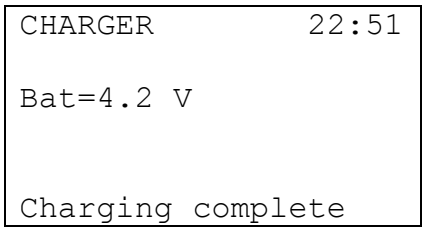
Figure 6 – Charging the WatchPAT™ device

4. The LCD will blink slowly and the following screen will be displayed:



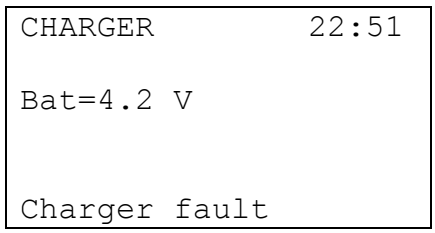
- The display will show **"CHARGER"** if you are charging with the AC adapter or **"PC HOST"** if you are charging with a computer.
- The current battery voltage is shown.
- Charge the battery the first time for approximately three hours. Thereafter recharging takes approximately 1-1.5 hours.

5. When charging is complete, the LCD will stop blinking and the following screen will be displayed:



6. Disconnect the AC adapter or communication cable. The WatchPAT™ device will switch off in 30 seconds.
7. Reseat the WatchPAT™ device in the wrist strap by gently sliding it back in until a click is heard.
8. Check that the oximetry module connector is properly connected to the WatchPAT™.

Should a charging error arise the LCD will blink rapidly and the following screen will be displayed.



3.2 Preparing the Oximetry Sensor

Use Nonin 8000JFW Flexi wrap pad and Nonin oximeter as supplied.

Figure 7 – Oximetry Sensor

1. If the sensor was previously used, carefully remove the used Flexi wrap pad from the sensor. Remove any remaining adhesive from the sensor – if necessary clean the sensor using 70% ethyl alcohol or isopropyl alcohol (IPA).
2. Place the new Flexi wrap pad with the printed side facing down on a flat surface.
3. Partially peel off the paper covering of the pad to expose the adhesive area around the two cut out sections.
4. Place the sensor on the pad with the back facing the sticky side placing the sensor's protrusions into the corresponding cutout sections as shown in Figure 8.

Reapply the paper covering of the pad.

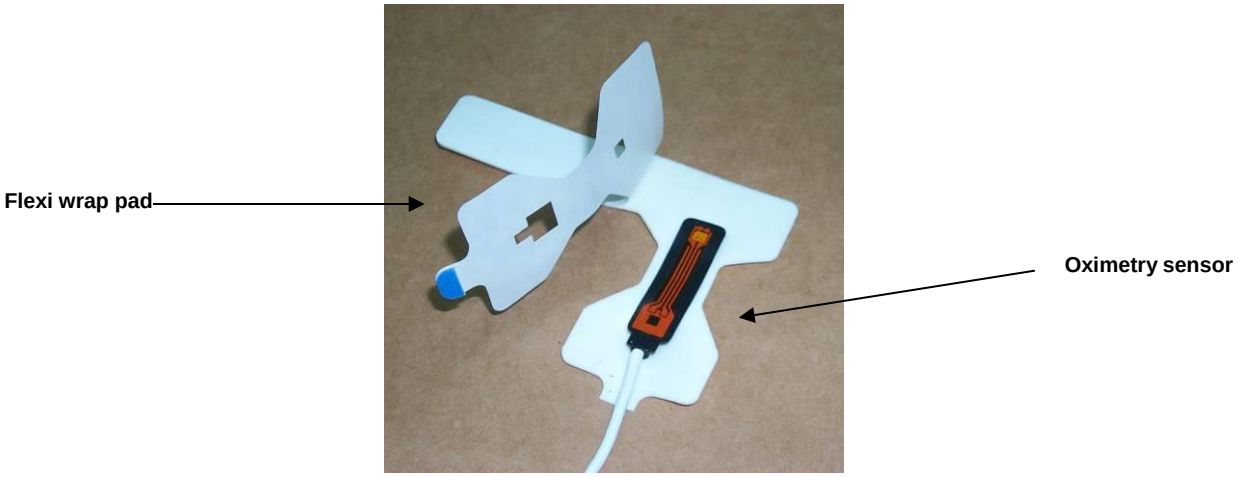


Figure 8 – Preparing the Nonin Oximetry Sensor

	Warning - Nonin sensor • Do not use a damaged sensor. If the sensor is damaged in any way, discontinue use immediately and replace the sensor. • Do not use caustic or abrasive cleaning agents on the sensors. • Do not autoclave or immerse in liquid of any kind.

3.3 Preparing the Snore and Body Position Sensor

Attach the small round double sided adhesive sticker to the white snoring sensor, by peeling off the cover on one side of the sticker.
Apply the body positioning adhesive sticker by attaching the sticker's smaller side to the back side of the body position sensor (without the Itamar logo).
For more details see Appendix A: WP200 Integrated Snoring + Body Positioning Sensor Operating

3.4 Preparing the Wrist Strap

The wrist strap requires no special preparation other than ensuring its cleanliness. You may clean it if needed. Take care not to allow the oximetry module or connector to get wet (see Figure 5). See section 6.1 for detailed cleaning instructions.

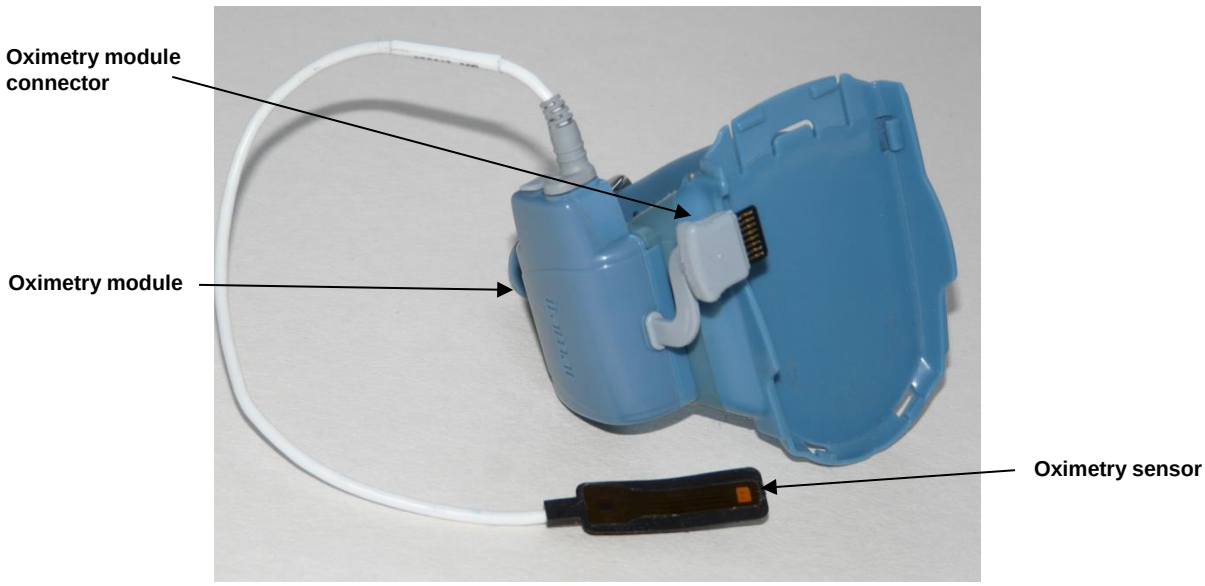


Figure 9 – Wrist Strap

3.5 Mounting the WatchPAT™ Device on the Wrist Strap

To mount the WatchPAT™ device on the wrist strap:

1. Gently slide the WatchPAT™ device into the wrist strap until a click is heard indicating that it is properly seated.
2. Connect the oximetry module connector (Figure 9) to the oximetry module port on the WatchPAT™ device (Figure 4).

3.6 Replacing the PAT® Probe

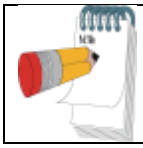
	Warning The PAT probe connector is very sensitive and therefore should never be left exposed. **Keep the connector connected to the probe at all times, especially during cleaning**. Replace the probe just before performing the Device test.

Remove a used probe by pressing the blue tab (clip) marked by the arrow in Figure 10, and then, holding the gray slider, gently slide it away from the probe – do not pull the slider off by pulling the cord, as it may damage the wiring. Properly dispose of used probes.

Figure 10 – Disconnecting the Probe

Figure 11 – Probe Disconnected

Connect a new probe by inserting the gray slider to the probe until the blue tab of the probe clicks into its place.

	**Note** Take care when inserting the gray slider to insure proper seating in the probe.

The WatchPAT™ device is now ready to perform a sleep study by the patient (Figure 12).

Figure 12 – A WatchPAT™ Device Fully Prepared

3.7 Preparing the WatchPAT™ Device for a New Study

Refer to the zzzPAT Software Manual for preparation of the WatchPAT™ device for a new study.

3.8 Testing the WatchPAT™ Device

Run the built-in self-diagnostic facility as described in Section 2.4 above.

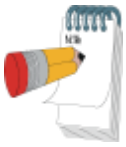
3.9 WP200 Device Self-diagnostic Test Results and Trouble-shooting

Should any of the self-diagnostic tests fail or report error messages refer to the trouble-shooting guide in Section 9.

3.10 Packing the Carrying Case

The following items must be placed inside the carrying case, in their respective compartments (see Figure 1 – Packed Device):

- The WatchPAT™ device mounted in the Wrist strap with the PAT® probe and oximetry sensor attached.
- Step-by-Step Reference Guide to the WatchPAT™ device
- Body Position and Snore sensor (optional)
- Cable for bracelet (optional for patient identification)
- 2 extra probes and AC adapter (optional for multi-night)

	**Note** Demonstrating the use of the WatchPAT™ device to the patient is important for obtaining reliable recordings and improving patient confidence.

4 OPTIONAL FUNCTIONS

4.1 Using the Integrated Snore & Body Position Sensor

The integrated sensor consists internally of two sensors: a snore sensor and a body position sensor.

A - Integrated Sensor Sensor Attachment

Figure 13 - The Snoring and Body Position Sensor

The integrated sensor is powered by the WatchPAT™ device and does not require a battery. It is automatically activated by the WatchPAT™ device when plugged into the Snore & Body position port.

The **snore sensor** is an acoustic decibel detector. It uses a very sensitive microphone that responds to snoring and other sounds in the audio range and converts them to a small analog voltage that provides a clear, reliable indication of the presence of these sounds.

The **body position** sensor uses a 3-axis accelerometer that provides a signal directly proportional to the patient's sleeping posture (supine, prone, right, left and sit).

See Appendix A: WP200 Integrated Snoring + Body Positioning Sensor Operating .

4.2 Tamper-Proof Testing with WatchPAT™ Device

The WatchPAT™ device Tamper-Proof bracelet is an add-on accessory used to authenticate the patient doing a sleep study and assure the study is recorded from the right person.

The bracelet is a single use small plastic band designed to be worn around the wrist of the hand. It contains an electronic circuit that signals to the WatchPAT™ device the integrity of the bracelet and a unique identification. During the night the bracelet is connected to the WatchPAT™ device using a small cable (see Figure 14).

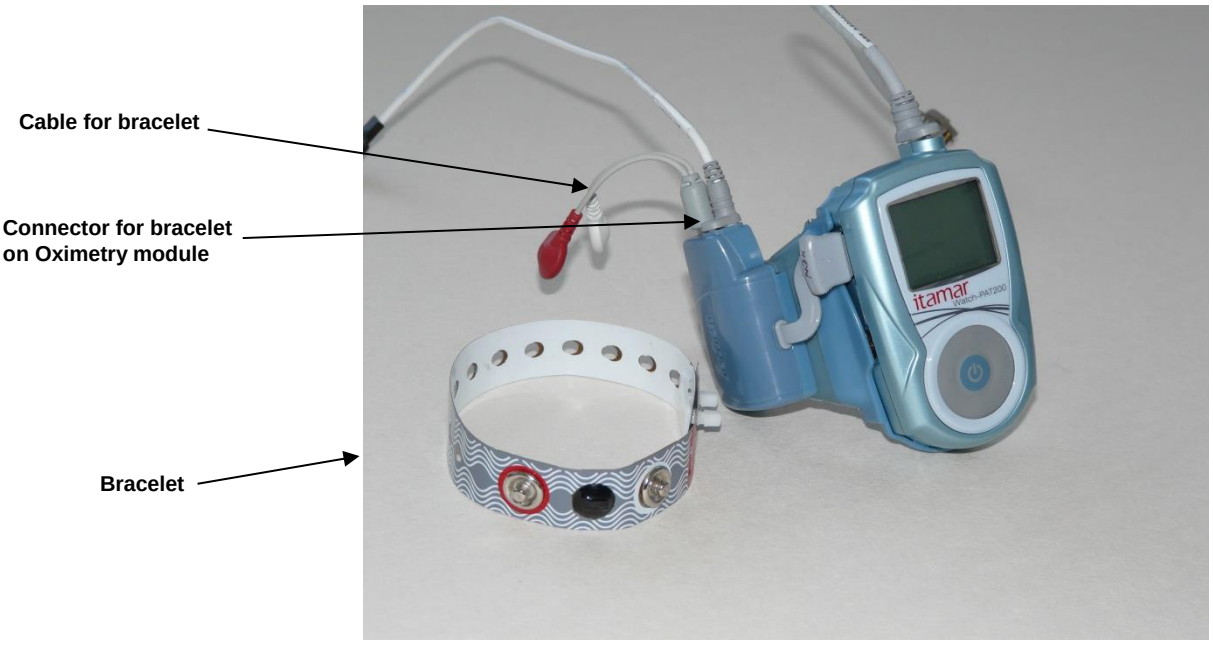


Figure 14 – WatchPAT™ Device with Tamper-Proof Bracelet

Before the device is given to the patient for home sleep study, the technician identifies the patient and secures the bracelet to the patient's wrist by a tamper-proof connector that ensures the bracelet will not be removed without cutting the Bracelet.

Figure 15 – Bracelet on Patient's Hand

When preparing the WatchPAT™ device for a sleep study, the technician pairs the Tamper-Proof Bracelet and the device and registers the bracelet's unique ID in the WatchPAT™ device (see Appendix B: Tamper-proof testing with the WP200 device).

The patient can wear the Bracelet for several days, continuing normal day-to-day activity until he is ready to record his sleep study. Before starting the recording, the patient will need to connect the Bracelet, via the bracelet's cable 2 connectors, to the WatchPAT™ device. The device will not start without connection to the paired Bracelet.

Figure 16 – WatchPAT™ Device with Cable for Bracelet

Figure 17 – WatchPAT™ Device with Bracelet

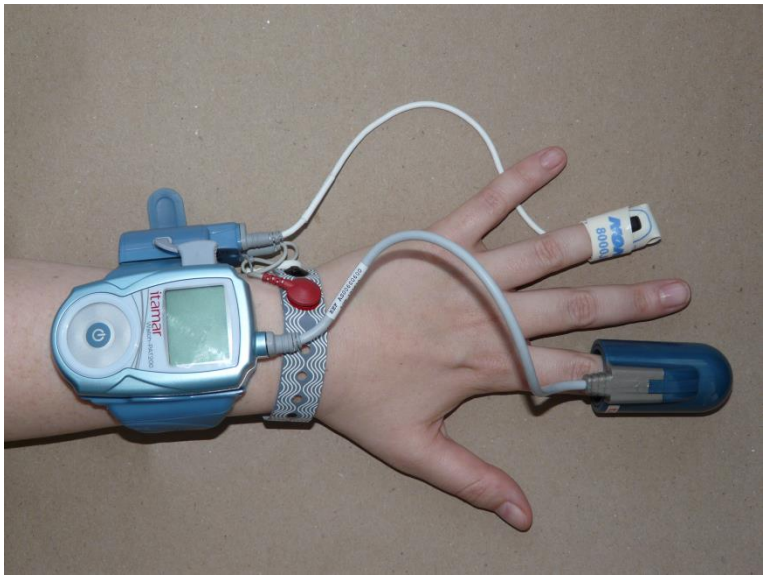


Figure 18 – Bracelet and WatchPAT™ Device on a Patient's Hand

During the recording the device will periodically check the Bracelet connectivity. The recording will be stopped if the connection to the Bracelet will be lost for the time exceeding a predefined limit.

After the recording is completed the patient can cut the Bracelet along the dotted line and return it with the device for study analysis.

Figure 19 – Cut the Bracelet at the Specified Location

4.3 Multi-night study

A patient study may be defined as multi-night study and the patient can sleep up to 3 nights with the same WatchPAT™ device. The multi-night option may be selected during New Study function (see zzzPAT Operation Manual).

If a 3 night multi-night option is selected the patient must replace the PAT® probe and charge the device between nights. Two extra PAT® probes and a WatchPAT™ device AC adapter must be added to the WatchPAT™ device case.

If a 2 night multi-night option is selected the patient must replace the PAT® probe only after the first night without the need to charge the device between nights. One extra PAT® probe must be added to the WatchPAT™ device case.

In case of multi-night study all of the patient studies will be loaded automatically to the zzzPAT during the upload (see zzzPAT Operation Manual).

Figure 20 – Case for a 3 Night Multi-Night Study

5 DATA DOWNLOAD AND ANALYSIS

Following the sleep study the WatchPAT™ device is returned to the referring sleep clinic for data downloading and analysis by the zzzPAT software.

To download and analyze the study data:

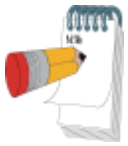
1. Connect the USB port of the WatchPAT™ device to the computer (see Figure 4) The WatchPAT™ device will switch off and then switch on in charging mode.
2. Activate the zzzPAT software to download and analyze the study data.

See the zzzPAT Software User Manual for detailed instructions.

6 MAINTENANCE

The WatchPAT™ device has been designed and manufactured to meet all safety requirements applicable to medical equipment. To ensure maximum safety of operation, the system should be used and maintained in strict compliance with the safety precautions, warnings and operating instructions provided in this Manual.

The system contains no user-serviceable parts. It should be maintained and serviced only by qualified service personnel, authorized by Itamar Medical Ltd.

	**Note** Please refer to the Service Manual or the support section of the Itamar Medical web site for preventive maintenance recommendations.

6.1 Cleaning

The various components of the WatchPAT™ system have different cleaning requirements:

- The WatchPAT™ device
- The wrist strap
- The oximetry sensor
- The Snore & Body Position sensor

6.2 Cleaning the WatchPAT™ Device

There is no need to clean the unit during ordinary operation. Should it become necessary to clean the WatchPAT™ device, proceed as follows:

Wipe parts with a clean, dry, lint-free cloth.

Clean casing with lint free cloth lightly moistened with 70% ethyl alcohol or isopropyl alcohol (IPA).

	Warning Clean the WatchPAT™ device only with the PAT® probe attached.

6.3 Cleaning the Oximetry Sensor

The Nonin pulse oximetry sensor has two parts, the single-use adhesive band and the optical sensor with cable and plug. The sensor/cable component is reusable, and should be cleaned as described in section 3.23.2.

6.4 Cleaning the Wrist Strap

You may clean the wrist strap with lint free cloth lightly moistened with 70% ethyl alcohol or isopropyl alcohol (IPA).

In order to disinfect the wrist strap by immersing into disinfecting liquid follow the steps:

Remove WatchPAT™ device from wrist strap

Remove Nonin module from wrist strap

Immerse wrist strap in 70% ethyl alcohol or isopropyl alcohol (IPA)

6.5 The PAT® Probe

The PAT® probe is designed for a single use only. It may not be cleaned and must be discarded and replaced before each study.

6.6 The Snore & Body Position Sensor

Using 70% ethyl alcohol, thoroughly clean both sensor and cable.

6.7 Handling

Handle with care:

- Use only the designated case for transportation
- Store at room temperature, and avoid direct sun light
- Do not expose the WP200 to extreme temperature or humidity conditions (such as storing in a car or bathroom)

6.8 Replacing the Oximetry Sensor

Should it become necessary to replace the oximetry sensor, proceed as follows:

1. Carefully disconnect the oximetry sensor from the oximetry module on the wrist strap. Make sure you remove the screw prior to disconnecting the sensor.
2. Carefully insert the connector of the new oximetry sensor cable to the oximetry sensor port in the oximetry module on the wrist strap (see Figure 21) noting proper alignment (3 round protrusions facing up). Make sure you secure back the screw.

	Warning Use only the original screws that belong to the WatchPAT™ device. Using different screws could harm the device.

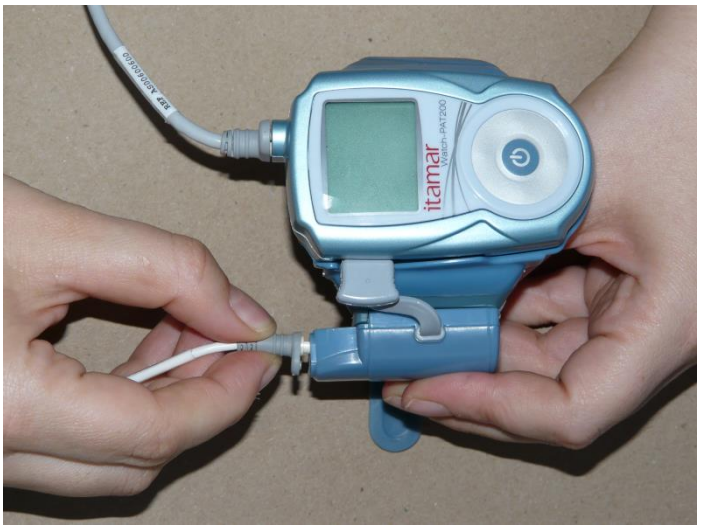
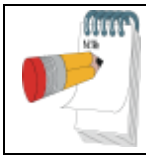


Figure 21 – Replacing Oximetry Sensor

	**Note** Please refer to the Service Manual or the support section of the Itamar Medical web site for preventive maintenance recommendations.

6.9 Replacing the PAT® Probe Cable

To replace the PAT® probe cable:

1. Carefully disconnect the PAT® probe cable from the WatchPAT™ device. Make sure you remove the screw prior to disconnecting the PAT® cable.

Figure 22 – PAT® Probe with Screw

2. Connect a new PAT® probe cable by gently inserting the connector into the WatchPAT™ device. Make sure you secure back the screw.

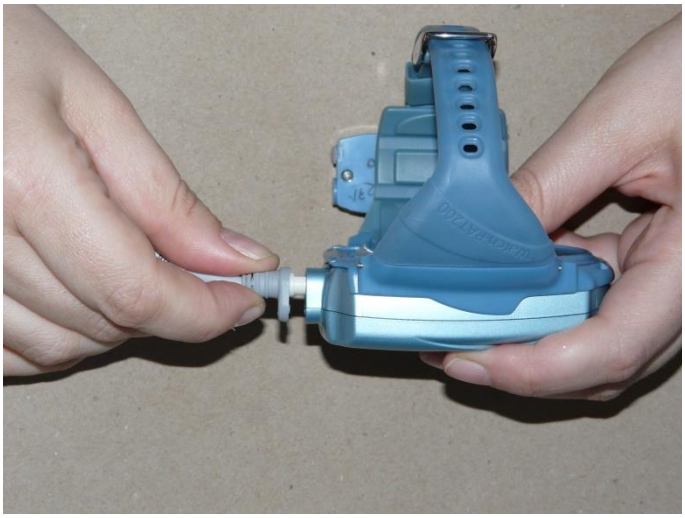
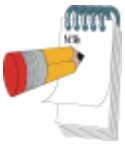


Figure 23 – Replacing the PAT® Probe

	Warning Use only the original screw that belongs to the WatchPAT™ device. Using different screw could harm the device.

	**Note** Please refer to the Service Manual or the support section of the Itamar Medical web site for preventive maintenance recommendations.

6.10 Replacing the Battery

	Warning Replace the battery only with an authorized battery provided by Itamar Medical Ltd.

In the event of a battery error message during the self-diagnostic tests or after charging, it may be necessary to replace the battery.
To replace the battery:

1. Open the battery compartment cover with a Phillips screwdriver.

2. Gently open the battery connector by disconnecting the 2 parts (you will need to remove the transparent tape that secures the battery connector closed).
3. Remove the battery.
4. Insert the new battery into the battery compartment.
5. Insert the 3 pin connector into the corresponding battery connector (one pin is longer so it may properly be inserted in only one direction). Secure the battery connector closed with a small piece of transparent tape.
6. Close the battery compartment cover and secure back the screw.

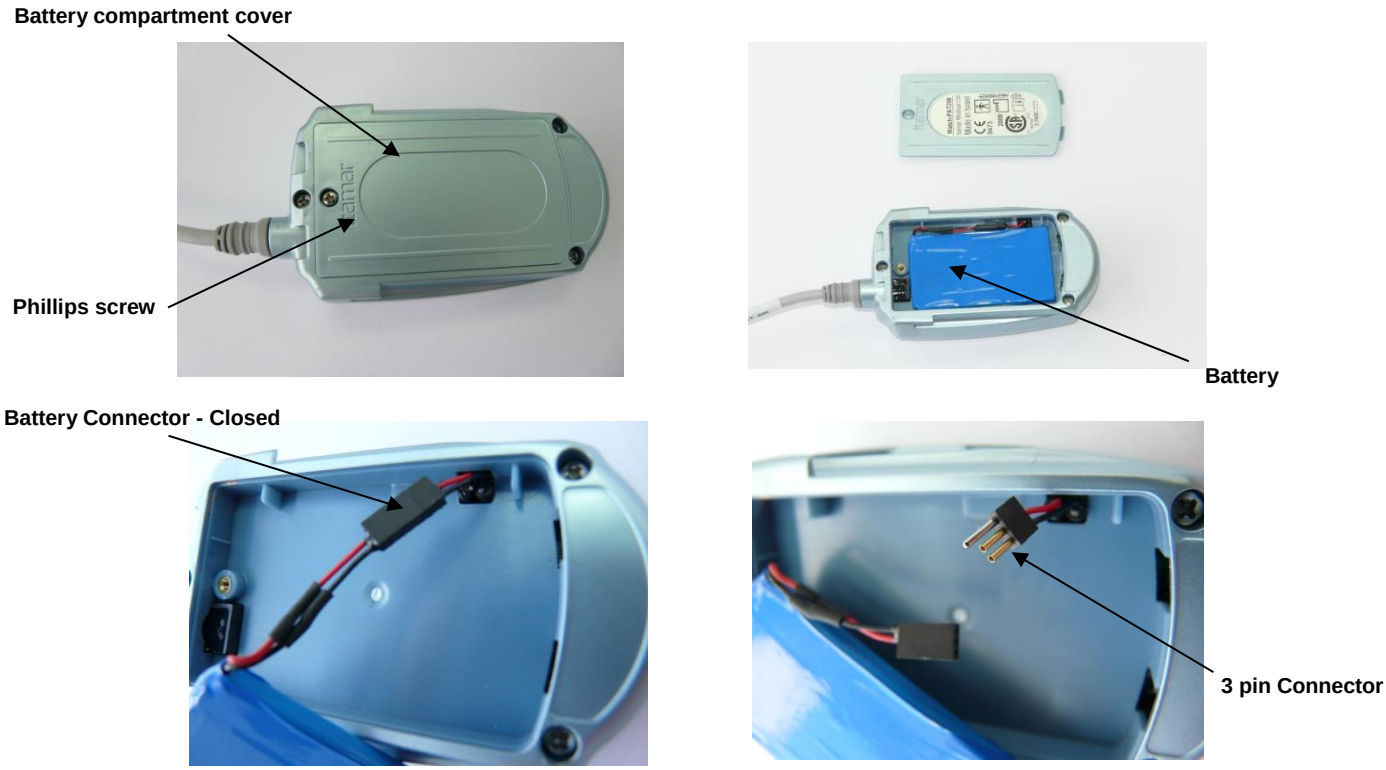
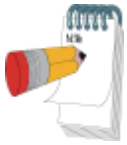


Figure 24 – Replacing the Battery

	**Note** Please refer to the Service Manual or the support section of the Itamar Medical web site for preventive maintenance recommendations.

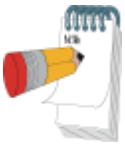
6.11 Setting the Time and Date of the WatchPAT™ Device

The WatchPAT™ device Time and Date can be set through the zzzPAT application. Refer to the zzzPAT Software Manual for preparation of the WatchPAT™ device for a new study.

6.12 Storing the WatchPAT™ Device

- The WatchPAT™ device should be stored in its carrying case at room temperature and low humidity.
- In order to preserve battery performance when the WatchPAT™ device is not in use, store with the battery fully discharged.
- Before storing the WatchPAT™ device, allow it to deplete the battery charge until it shuts down automatically.

7 APPLYING THE WATCHPAT™ DEVICE

	**Note** These instructions are designed to help the patient use the WatchPAT™ device **after** seeing a demonstration by trained personnel of how to mount the probes on his/her fingers and correctly operate the WatchPAT™ device .

The following detailed instructions are summarized in the patient's step-by-step reference guide. They are written as if the reader is the patient using the WatchPAT™ device.

7.1 Preparing for Use of the WatchPAT™ Device

- Before using the WatchPAT™ device, review the following notes:
- Remove tight clothing, rings, watches and jewelry from your non-dominant hand and wrist and from your neck and chest.
- The probes may be worn on any two fingers of your non-dominant hand. We recommend that the oximetry sensor and PAT® probe be attached to the ring and index fingers respectively (Figure 25). The following instructions relate specifically to these fingers. Patients with very large fingers may use their small finger (pinky) for the PAT® Probe.
- Ensure that fingernails of fingers that will be monitored are well trimmed, (less than 1mm from nail bed) with no jagged edges. Clip and file nails, if necessary.
- Remove artificial fingernails or dark nail polish from the monitored fingers.
- Patient sensitivity to Nonin oximetry sensor may vary due to medical status or skin condition. Discontinue use if the patient exhibits allergic reactions to the adhesive material.
- Do not stretch the Nonin adhesive tape while applying the oximetry sensor. This may cause inaccurate readings or skin blisters.
- You may need some assistance putting on the WatchPAT™ device. If needed have someone present to assist you.
- Make sure the room you are sleeping in is as quiet as possible during the night, turn off any possible noise sources. When using the SBP it is advised to sleep alone in the room.

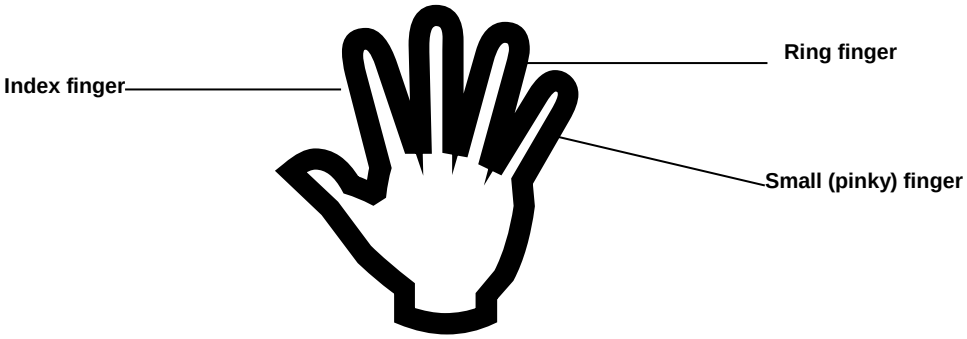


Figure 25 – Finger Designation

7.2 Applying the WatchPAT™ Device

To apply the WatchPAT™ device to your wrist:

1. Open the carrying case and take out the wrist strap with the WatchPAT™ device mounted. All parts should already be connected, as illustrated in Figure 12.
2. Ensure that the WatchPAT™ device is firmly seated in the wrist strap. If not, gently seat the WatchPAT™ device in the strap by sliding it into its seating position. You will hear a click when the WatchPAT™ device is properly seated in the strap.
3. Place the wrist strap with the WatchPAT™ device on the non-dominant arm and close it snugly but not tightly. Ensure that the rounded end is towards the body and the open end towards the fingers. You may find it convenient to place the wrist strap with the WatchPAT™ device face down on the table and then place the back of the wrist over the wrist strap in order to fasten the straps (Figure 26).
4. At this point both probes are hanging loose (Figure 27).

.

Figure 26 – Putting On the Wrist Strap

Figure 27 – Wearing the WatchPAT™ Device

7.3 Applying the Oximetry Sensor

Now you will attach the oximetry sensor to your ring finger, as was demonstrated to you and is illustrated in the figures below.

Please proceed as follows:

1. Remove the adhesive strip from the unit (see Figure 28).
2. Position the oximetry sensor on your ring finger with the wire on the bottom side of the finger (see Figure 29) – the finger should reach the centerline marker on the pad.
3. Fold the bottom short flaps around your finger (see Figure 29).
4. Fold top flap over the finger and fold the short flap around your finger (see Figure 30).
5. Complete this procedure by wrapping the long flap around the short wrapped flaps (see Figure 31).
6. Ensure that the dotted line of the Flexi wrap pad is properly located, as indicated by the arrow (see Figure 32), and that the two square black protrusions are opposite one another.
7. The oximetry sensor is now attached. When the WatchPAT™ device is turned on, the sensor will glow red.

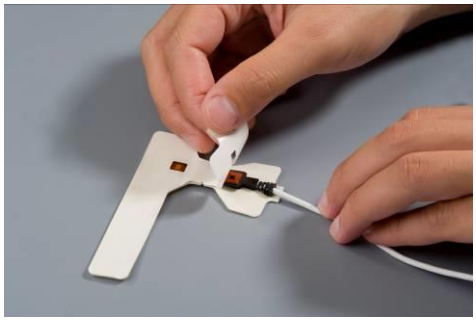


Figure 28 – Removing Adhesive Cover

Figure 29 – Positioning Oximetry On Ring Finger

Figure 30 – Fold Top Flap and Short Flap

Figure 31 – Wrap The Long Flap

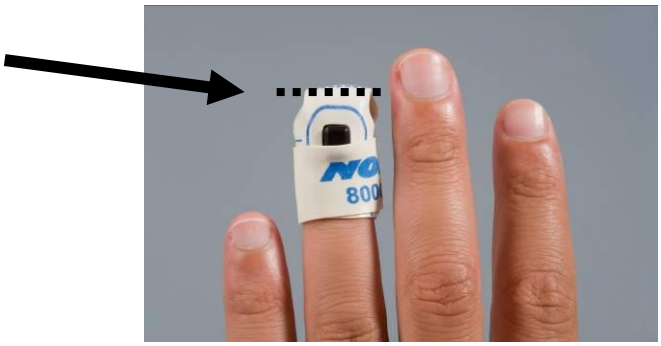
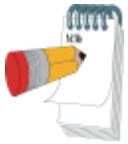


Figure 32 – Flexiwrap Line Indication

7.4 Attaching the PAT® Probe

Proper probe placement is critical for good performance.

	**Note** The tabs inside the probe should be removed only **AFTER** the finger is inserted into the probe.

To attach the PAT® probe:

1. Insert your index finger (or other if so instructed) gently into the probe until it reaches the end (see Figure 33).
2. Make sure that the paper tab marked TOP is above your nail and the tab marked BOTTOM is below your finger.
3. Detach and gradually remove the tab marked TOP slowly and firmly while pressing the tip of probe against a hard surface (WatchPAT™ case, table, etc.) until the tab is completely removed from the probe (Figure 34).
4. Optional – Only if bottom tab is present:
   Detach and pull on the tab marked BOTTOM slowly and firmly towards the back of your hand, while still pressing against a hard surface until the tab is completely removed (Figure 35). You might feel a slight suction once the tabs are removed.

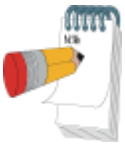
   The PAT® probe is now attached (Figure 36).

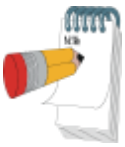
Figure 33 – Placing Finger in PAT® Probe

Figure 34 – Removing TOP Tab

Figure 35 – Removing BOTTOM Tab

Figure 36 – Wearing the WP200 – Ready for Sleep

	**Note** DO NOT remove the PAT® probe before the night study is terminated. Once the probe is removed it cannot be re-attached.

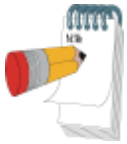
	**Note** If the Snore & Body position sensor is included in the WatchPAT™ device case see Appendix A: WatchPAT™ device Integrated snoring + body positioning Sensor operating instructions

7.5 Switching On the WatchPAT™ Device

You are now ready to switch on the WatchPAT™ device.

Just before you lie down to go to sleep, firmly press the ON/Enter center button (Figure 3) until the LCD display lights up. After a short delay the LCD will display "Good Night! Recording…"

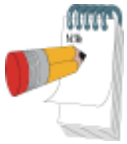
```
PATIENT       22:51

GOOD NIGHT!!!

Time elapsed=9:50
Recording…
```

	**Note** To conserve the battery the LCD display will switch off after a few seconds. Pressing any button will restore the display for about 30 seconds.

7.6 When You Wake Up

When you awake, remove the WatchPAT™ device from your arm as follows:

1. Remove both probes from your fingers.
2. Take off the wrist strap.
3. Place all parts in the carrying case.

	**Note** Pressing the center button does not switch off the WatchPAT™. The oximetry sensor red light will remain lit. Approximately ten hours after the WatchPAT™ is turned on, it will switch off. This is normal.

7.7 Important Notes

Wearing the WatchPAT™ device should not cause any discomfort or pain. If you experience wrist or arm discomfort, loosen up the wrist strap. If the discomfort is not alleviated immediately, call the service number.

- Do not attempt to connect or disconnect any part of the unit.
- Do not try to introduce any foreign object into the unit.

- Do not try to connect the unit to an electrical supply or any other unit, machine or computer.
- If any part appears disconnected or does not resemble the illustrations, call the service number for assistance.
- Do not, under any circumstances, attempt to fix the problem yourself.

If you have any questions about using the machine, before, during or after your at-home recording session, call the service number.

8 PATIENT TRAINING – GUIDELINES

8.1 Walk Through the Process of Using the WatchPAT™ Device

- Product introduction – WatchPAT™ device, wrist strap, PAT® probe, oximetry sensor
- WatchPAT™ device and wrist strap attachment
- Probe and sensor attachment
- Switch on
- Ending the study

8.2 Product Introduction

- Open the Demo-case and introduce the 'Quick guide step-by-step' instruction manual.
- Introduce each component by its name and identify it as in the figures in the manual.

8.3 Applying the WatchPAT™ Device

Use the Demo Kit.

- Demonstrate how to apply the WatchPAT™ device on your wrist while following the 'step by step' guidelines and referring to the relevant figures.
- Demonstrate the following:

1. **Hand Preparation**
    - Remove rings, watches and jewelry from hand
    - Remove fingernail polish and artificial nails
    - Make sure finger nails are closely trimmed
2. **Attaching the Snore & Body Position Sensor (optional)**
    - The snoring sensor is attached to the base of the patient's neck.
    - To position the sensor place the snoring sensor with the microphone side (black opening) against the skin using the round double sided adhesive sticker.
    - Make sure the sensor is tight against the skin.
    - Secure the snoring sensor in place with medical tape.
    - Locate the body position sensor on the chest bone.

- Pull the paper tabs all the way off the body position sensor while attaching it on the skin.

3. **Wearing the Wrist Strap**
   - Should be comfortable, not too tight.
4. **Attaching the WatchPAT™ Device**
   - Make sure the WatchPAT™ device is properly mounted on the wrist strap. If it is loose, gently slide it in until you hear a click.
5. **Attaching the Oximetry Sensor**
   - Before PAT® probe attachment
   - Demonstrate proper placement of the finger on the Flexi wrap pad – note the position of the fold line, and that the two black square protrusions are opposite each other.
   - Folding the flaps of the Flexi wrap pad to secure sensor properly.
   - Make sure it is not too tight
6. **Attaching the PAT® Probe**
   - Insert finger all of the way into the probe
   - Press tip of probe against a hard surface (WatchPAT™ device case, table, etc.) while removing tabs in order to keep the finger from moving inside the probe
   - Tab(s) must be fully removed
   - The probe is limited to a SINGLE USE. Do not remove probe during the night.

8.4 Switching on the WatchPAT™ Device

- Demonstrate switching on the WatchPAT™ device by pressing the round center button
- Push button firmly until the LCD display lights up
- The oximetry sensor light will glow red during the entire test

8.5 Removing the WatchPAT™ Device

- Demonstrate how to remove the WatchPAT™ device and place it back in the carrying case.
- The oximetry sensor light will keep glowing red.

- The WatchPAT™ device doesn't switch off – once turned on it will record until the battery is exhausted.

8.6 Patient Training

- Following your demonstration have the patient attach the demo device by himself.
- Verify that the attachment is properly done. Especially monitor carefully attachment of the oximetry sensor.

8.7 Review Safety, General and Functional Issues

- Avoid exposing the WatchPAT™ device to extreme conditions (high temperature, high humidity)
- Provide a telephone number to call in case of questions or problems.

9 TROUBLESHOOTING GUIDE

9.1 Operator Error Messages

If an error message is displayed while performing the self-diagnostic tests, take the actions specified below. If the problem persists contact Itamar or an authorized representative.

Table 1 – Operator Troubleshooting

Error	Possible Reason	Action
File error		
Not loaded	Study not initialized for new patient	Connect device to PC and perform New Study in zzzPAT
Battery error % full	Battery defective or uncharged	Charge battery or replace
Probe error		
Used	Probe previously used	Replace probe
Missing	Probe absent	Attach probe
Bad	Probe is defective	Replace probe
Oximetry sensor error		
No sensor	Sensor absent	Replace sensor
Disconnected	Sensor disconnected	Connect sensor cable to port
No communication	Module not connected	Check cable connection
Hardware status error code	WatchPAT™ device defective	Consult Itamar or authorized representative
SBP disconnected even if it is connected	P200 or SBP sensor defective	Consult Itamar or authorized representative
RTC faulty	WatchPAT™ device defective	Consult Itamar or authorized representative
Short recording time	Patient removed the WatchPAT™ device or probe from hand prematurely	Explain proper use to patient
	Insufficient battery charge caused early termination of recording	Recharge battery and try again
	Damaged WatchPAT™ device	Contact your authorized sales representative

9.2 Patient Error Messages

If an error message is displayed when the patient powers on the WatchPAT™ device, the patient should take the actions specified below. If the problem persists the patient may contact Itamar or an authorized representative directly.

Table 2 – Patient Troubleshooting

Error	Possible Reason	Action
Oximetry sensor light turns off while WatchPAT™ device is on.	Oximetry sensor plug not fully inserted	Verify that oximetry sensor plug is fully inserted into the WatchPAT™ device
	Faulty oximetry sensor	Check the oximetry sensor probe for damage and replace if necessary
Oximetry sensor disconnected	Sensor not properly connected or faulty	Check connection. If problem persists replace sensor
WatchPAT™ device does not switch on	ON button not activated	Press the ON button firmly for at least 3 seconds
	PAT® probe not connected	Ensure probe is connected and try again
Probe disconnected	Probe may not be connected, or may be a used probe	Check connection of probe to cable and cable to the WatchPAT™ device; check if probe has been previously used and replace with new probe if necessary
Hardware code	WatchPAT™ device failure	Contact Itamar or authorized representative

10 SPECIFICATIONS

Table 3 – WatchPAT™200 Device Specifications

Properties		**Description**
PAT® Probe		Itamar's proprietary probe only
Recording Time		10 hours (minimum)
Oximetry Probe		Custom Nonin 8000J Flex Sensor
Channels		Measuring 4 signals: PAT, Pulse rate, Oximetry, Actigraphy
Sample Resolution		PAT® and Actigraph – 12 bit; oximetry – 1% Snoring – 12 bit, Body Position – 5 discrete states
User Interface		LCD display
Accuracy	*Pulse rate* *Amplitude* *Oximetry*	30-150 ± 1 bpm 0-0.5V ± 10% 70-100% ± 2 digits (in % units)
PAT® Channel	*Bandwidth*	0.1-10 Hz
Data Storage	*Media*	Micro SD card
	Capacity	64 MB (minimum)
	Format type	Formatted to FAT 32
Power Supply	*Battery*	Proprietary, rechargeable Lithium Ion Battery
	Capacity	> 500-700 mAh
	Cell Type	Lithium Ion cell type
	Internal Charger	Proprietary Lithium Ion battery charger
	External Power Supply	5V DC, 5W with USB connector
Operating Voltage		3.3 V
Temperature	*Operation*	0^0C to 40 ^{0}C
	Storage (Device)	-20^0C to 40 ^{0}C
	Transport (Device)	-20^0C to 60 ^{0}C
	Storage & Transport (Probe)	0^0C to 40 ^{0}C
Humidity	*Operating*	10% – 93% (non-condensing)
	Storage & Transport	0% – 93% (non-condensing)
Atmospheric pressure	*Operating & Storage*	10 – 15 psi
	Transport	8 – 15 psi
Dimensions	*L x W x H*	80 x 50 x 20 mm
	Weight	170 gr (excluding PAT® probe weight of 20 gr)

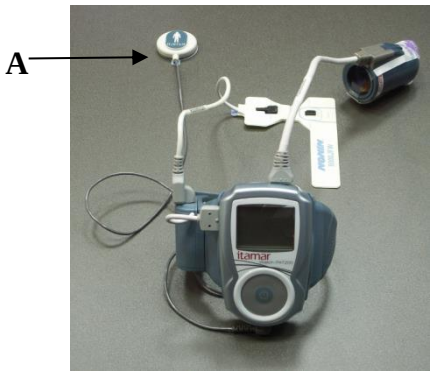
APPENDIX A: WP200 INTEGRATED SNORING + BODY POSITIONING SENSOR OPERATING INSTRUCTIONS

Must be used with zzzPAT v 4.3 and above, and WatchPAT™200

Thank you for purchasing an Integrated Snore & Body Position Sensor.

Description

The integrated sensor consists internally of two sensors: a snore sensor and a body position sensor.



A - Integrated Sensor

Sensor Attachment

The integrated sensor is powered by the WatchPAT™ device and does not require a battery. It is automatically activated by the WatchPAT™ device when plugged into the Snore & Body position port.

The **snore sensor** is an acoustic decibel detector. It uses a very sensitive microphone that responds to snoring and other sounds in the audio range and converts them to a small analog voltage that provides a clear, reliable indication of the presence of these sounds.

The **body position** sensor uses a 3-axis accelerometer that provides a signal directly proportional to the patient's sleeping posture (supine, prone, right, left and sit).

Indications of use

The integrated Snoring & Body position sensor is an accessory of the WatchPAT™ home care device for use with patients suspected to have sleep related breathing disorders. The integrated sensor monitors the snoring level, which aids in the evaluation of the severity of sleep related breathing disorders, and the body position which aids in the evaluation of the type of sleep related breathing disorders.

Preparing the sensor

- Attach the round double sided adhesive sticker to the blue side of the sensor.

Applying the sensor

Make sure the room you are sleeping in is as quiet as possible during the night, turn off any possible noise sources. When using the SBP it is advised to sleep alone in the room.

- The sensor is attached on the patient's chest right under the sternal notch. The sternal notch is the little U shape where the collar bones meet at the top of the breast bone.
- To position the sensor attach it with the man image standing up, after peeling off the round adhesive sticker and pressing against the skin.
- Make sure the sensor is tight against the skin.
- Secure the sensor in place with medical tape.

Cleaning the sensor

Using 70% ethyl alcohol, thoroughly clean both sensor and cable.

SPECIFICATIONS		
Snoring Sensor Technology	Sensitive microphone	
Body Position Sensor Technology	3-axis Accelerometer	
Signal Amplitude	0-3.3 V	
Connector Type	1 mm medical safety connector plug from Plastics1 *Wire Length:* 3.2 foot (100 cm)	
Physical Size	1.3 inch diameter (32 mm diameter)	
Weight	12 gr	
Warranty	6 months	
Temperature	*Operation*	0 to 40 ^{0}C
	Storage	-20 to 40 ^{0}C
	Transport	-20 to 60 ^{0}C
Humidity	*Operating, Storage & Transport*	0% – 93% (non-condensing)
Atmospheric pressure	*Operating & Storage*	10 – 15 psi
	Transport	8 – 15 psi

Snoring and Body Position Accuracy

This section gives statistical performance measure for Itamar Medical's SBP sensor, when used with the WatchPAT™ device.

I. Body Position

The body position measured by the WatchPAT™ device with Itamar SBP sensor, was compared to the gold standard, manual scoring of the video recording of 31 patients, in 1 minute's epochs (total of 7111 epochs) during sleep.

The Agreement between the device and the video recording was 90%.

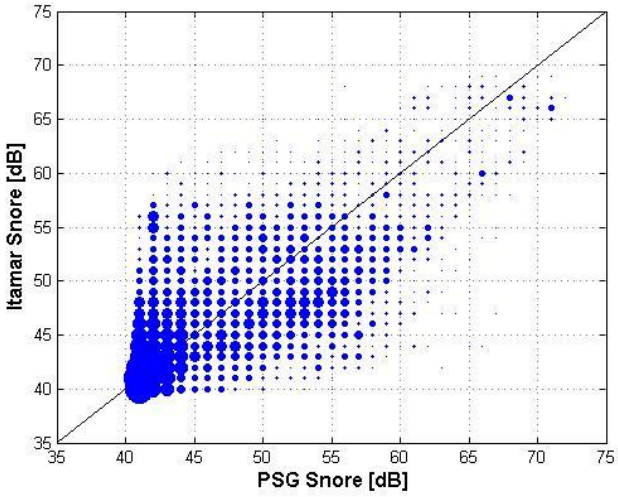
Simple Kappa agreement value was 0.8185 (95% confidence level of 0.8059 and 0.8311).

II. Snoring

The snoring level measured by the WatchPAT™ device with Itamar SBP sensor, was compared to a gold standard PSG dB-meter placed 1 meter from patient's head. The study included 26 patients, and the analysis was done in 30sec epochs.

The correlation coefficient was calculated using Pearson method, assuming a linear relation between the results of the two devices. A statistically significant correlation was calculated between the two devices: r=0.65 p value<0.0001.

The next figure shows a scatter plot of sleep disturbance Index produced by the WatchPAT™ device and dB-meter, with linear regression line.

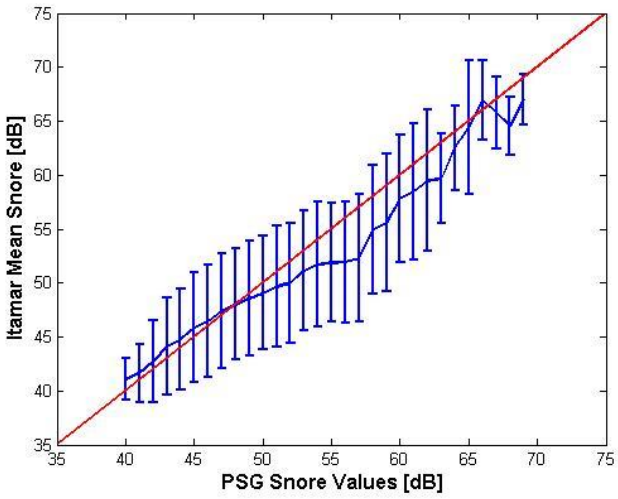


An estimation of the error in each snoring level was calculated by looking at the WatchPAT™ device measurement cut by the results of dB-meter in intervals of 1 dB in the range of above 40dB (below 40 dB was considered not clinically significant being background noise). A high correlation was observed between the results of the two devices for the range of 40-70dB (where sufficient data points were gathered), meaning the resemblance in the results uniformly existed for all the snore levels measured.

The next table presents the statistics of WatchPAT™ device measurements per dB-meter calculation at that range.

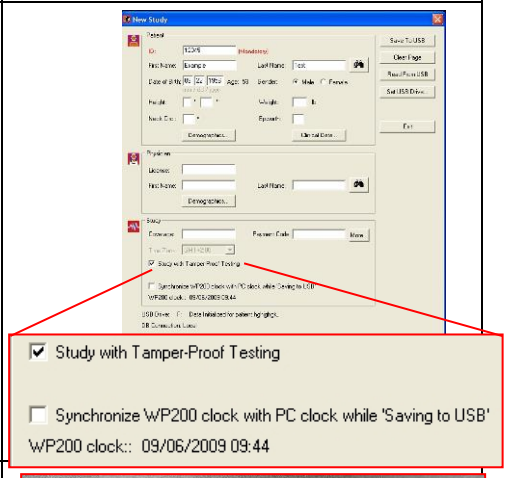
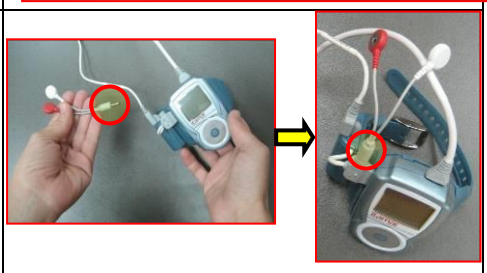
PSG DB Value	N	Mean	Std	Coef. Of Variation [%]	Min	Max	Median	Lower 95% CI	Upper 95% CI
40	2033	41.10	1.89	4.60	40	54	40	41.01	41.18
41	1319	41.61	2.67	6.43	40	54	41	41.47	41.76
42	908	42.68	3.79	8.88	40	62	41	42.44	42.93
43	746	44.12	4.49	10.19	40	58	42	43.80	44.44
44	719	44.75	4.65	10.39	40	65	43	44.41	45.09
45	643	45.90	5.07	11.04	40	59	45	45.51	46.30
46	602	46.45	5.17	11.13	40	59	46	46.04	46.86
47	590	47.39	5.31	11.21	40	66	47	46.96	47.82
48	568	48.03	5.17	10.76	40	61	49	47.60	48.45
49	414	48.56	5.33	10.97	40	64	49	48.05	49.08
50	369	49.07	5.27	10.75	40	61	49	48.53	49.60
51	334	49.68	5.66	11.39	40	63	50	49.07	50.28
52	335	50.00	5.58	11.17	40	64	51	49.39	50.59
53	311	51.18	5.56	10.86	40	63	51	50.56	51.79
54	253	51.71	5.78	11.19	40	66	52	51.00	52.42
55	209	51.85	5.49	10.59	40	66	52	51.11	52.60
56	182	51.91	5.62	10.82	40	64	52	51.09	52.72
57	129	52.29	5.91	11.30	41	64	52	51.26	53.32
58	95	54.94	5.94	10.82	42	67	55	53.73	56.15
59	66	55.53	6.37	11.47	42	66	55.5	53.97	57.10
60	72	57.82	5.92	10.24	44	66	58	56.43	59.21
61	58	58.48	6.31	10.78	43	68	58.5	56.82	60.14
62	43	59.47	6.56	11.02	46	68	60	57.45	61.48
63	32	59.63	4.15	6.96	50	67	59	58.13	61.12
64	15	62.53	3.93	6.28	56	68	64	60.36	64.71
65	22	64.41	6.21	9.64	49	70	67	61.66	67.16
66	48	66.90	3.66	5.48	59	70	68.5	65.83	67.96
67	42	65.76	3.28	4.99	60	71	67	64.74	66.78
68	27	64.56	2.67	4.13	55	68	65	63.50	65.61
69	6	67	2.37	3.53	64	70	67	64.52	69.48

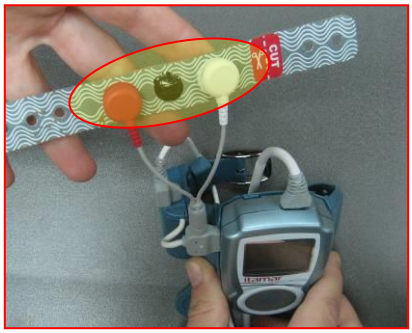
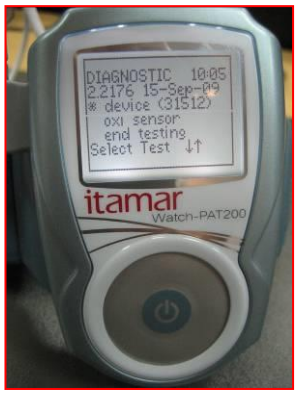
The results are also presented in the next figure. The figure presents the mean WatchPAT™ device with SD error bar.

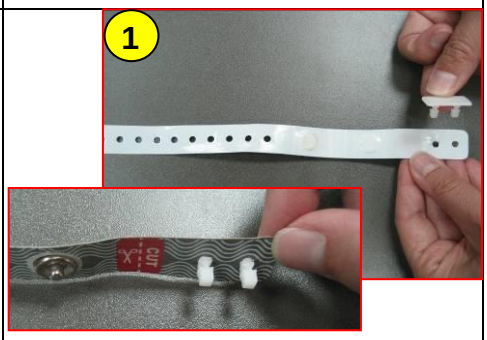


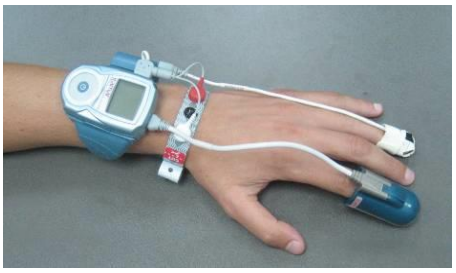
Summary statistics (mean ± SD) of WatchPAT™200 device by dB-meter levels

APPENDIX B: TAMPER-PROOF TESTING WITH THE WP200

			Action	Comment
Important Notes		Important Notes –	This short guide is designed to instruct a **trained operator of the WatchPAT™ device** on how to perform a Tamper-Proof Testing with the bracelet & the WatchPAT™ device. For complete WatchPAT™ training & instructions please refer to the WatchPAT™ device user manual and to the zzzPAT user manual.	Make sure the zzzPAT version is: **4.2.58 or higher** Make sure the WatchPAT™ device embedded software version is: **2.2176 or higher** Make sure you enabled the "Tamper-Proof Testing" option from the zzzPAT "Setup" menu → "General Settings"
Study Preparation	1.	Preparing a New Study on zzzPAT	While preparing the new study on the zzzPAT (refer to the user manual for detailed instructions), check the box "Study with Tamper-Proof Testing" at the bottom of the "New Study" screen. <u>Note:</u> Once you enable this option you will HAVE to use a bracelet for the night study. The WatchPAT™ device will NOT function without a bracelet connected to it.	
Bracelet Preparation	2.	Bracelet	Select a Tamper-Proof Bracelet for the study.	
	3.	Connecting the Cable to the WP200	Connect the gray cable with the red and white connectors to the WatchPAT™ device socket.	

			Action	Comment
Bracelet Preparation	*4.*	Connecting the Bracelet	Connect the red and white connectors (other side of the gray cable) to the red and white snaps on the bracelet respectively.	
	5.	Pairing the WP200 and the Bracelet: Site-Diagnostic Test	Perform the regular site diagnostic test ("device test" & "oxi test" as described in the user manual). Make sure the bracelet is connected before starting the test. After tests passed successfully, disconnect the bracelet from the WatchPAT™ device and store them together. <u>Note:</u> Once the device testing has been done with the bracelet connected – the SPECIFIC bracelet must be used with the specific WatchPAT™. NO OTHER BRACELET WILL WORK WITH THIS WatchPAT™ device. (A unique ID of this bracelet is registered in the WatchPAT™ System.)	

			Action	Comment
Subject Setup	1	Placing the Bracelet on the Subject	Make sure you have all 3 parts: the bracelet and two white plastic parts. Place the bracelet upside down on a flat surface (white side facing up). Insert the white plastic part into the two separated holes (flat side facing up).	
	2		Wrap the bracelet around the wrist of the non-dominant arm (tested arm) of the subject. Insert the white plastic parts into the holes. Make sure it is snug but not too tight.	
	3		If there is some loose strap left, fold it and re-insert it into the holes. DO NOT CUT LOOSE STRAP – CUTTING IT WILL RENDER BRACELET UNUSABLE	
	4		Secure the bracelet by placing the second white plastic part on-top of the first. Make sure it is secured tightly.	

			Action	Comment
Explain to Subject	*6.*	Explain to Subject	The subject may choose to perform the night study during any night during the next week. It's OK to shower with the bracelet. Instruct subject to turn on the WatchPAT™ device only after it is connected to the bracelet. THE BRACELET IS NOT TO BE REMOVED UNTIL THE NIGHT STUDY IS COMPLETED. Removing the bracelet before or during the night will cause the device to shut down. In the morning, instruct to cut the bracelet along the dotted line, using small scissors and to put it in the WatchPAT™ device case along with all the other parts (DO NOT THROW BRACELET AWAY). Do not try to connect ANY other device to the bracelet.	

APPENDIX C: LICENSE AGREEMENT

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APPENDIX D: REGULATORY REPRESENTATIVE

Itamar Medical's authorized regulatory representative is:

MEDES Ltd.

5 Beaumont Gate, Shenley Hill,
Radlett, Hertfordshire WD7 7AR.
England
Tel: +44 208123 8056
Tel / Fax: +44 1923859810

APPENDIX E: DESCRIPTION OF THE WATCHPAT™200 PROBE

The WatchPAT™ PAT® probe is an opto-pneumatic finger-mounted probe.
Its role is to continuously measure the relative state of the vasomotor activity in the distal part of the finger based on a plethysmographic method. The PAT®probe is designed to cover the distal part of the finger with a uniform pressure field extending to the tip of the finger. This design prevents venous blood pooling, engorgement and stasis, which inhibits retrograde venous shock wave propagation, and allows partial unloading of arterial wall tension that significantly improves the dynamic range of the measured signal. The optic component of the probe measures the optical density related changes of the arterial blood volume in the digital arteries, associated with each heartbeat. Peripheral arterial constrictions, when present, are shown by attenuation in the PAT signal amplitude, a marker of sympathetic activation.

The PAT® probe is an integral part of the WatchPAT™ device.

APPENDIX F: MANUFACTURING DECLARATION ACCORDING TO IEC 60601-1-2

Electromagnetic Compatibility

Notes

• The WatchPAT™200 requires special precautions with regard to electromagnetic compatibility.
• It must be installed and prepared for use as described in section 11 - Preparation for Sleep Study.
• Certain types of mobile telecommunication devices such as mobile telephones are likely to interfere with the WP200.
• The recommended separation distances in this section must therefore be complied with.
• The WP200 must not be used near or on top of another device. If this cannot be avoided, it is necessary – before clinical use – to check the equipment for correct operation under the conditions of use.
• The use of accessories other than those specified or sold by Itamar Medical as replacement parts may have the consequence of increasing the emissions or decreasing the immunity of the unit.

Electromagnetic Emissions

- WP200 is intended for use in the electromagnetic environment specified in the following tables 1, 2, 4 and 6 below.
- The user and/or installer of the unit must ensure that it is used in such an environment.

Table 1 – from IEC 60601-1-2:2007

Guidance and manufacturer's declaration – electromagnetic emissions – WP200		
The **WP200** is intended for use in the electromagnetic environment specified below; The customer or the user of the **WP200** should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The **WP200** uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The **WP200** is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class B	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 2 - from IEC 60601-1-2:2007			
Guidance and manufacturer's declaration – electromagnetic immunity – WP200			
The **WP200** is intended for use in the electromagnetic environment specified below; The customer or the user of the **WP200** should assure that it is used in such an environment.			
Immunity test	**IEC 60601-1-2** **Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines Not Applicable	Mains power quality should be that of a typical public low-voltage power supply network that supplies buildings used for domestic purposes, commercial or hospital, clinic environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical public low-voltage power supply network that supplies buildings used for domestic purposes, commercial or hospital, clinic environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 .	<5 %UT (>95 %dip in UT) for 0,5 cycle 40 %UT (60 %dip in UT) for 5 cycles <5 %UT 70 %UT (30 %dip in UT) for 25 cycles <5 %UT <5 %UT (>95 %dip in UT) for 5 s	<5 %UT (>95 %dip in UT) for 0,5 cycle 40 %UT (60 %dip in UT) for 5 cycles <5 %UT 70 %UT (30 %dip in UT) for 25 cycles <5 %UT <5 %UT (>95 %dip in UT) for 5 s	Mains power quality should be that of a typical public low-voltage power supply network that supplies buildings used for domestic purposes, commercial or hospital, clinical environment. If the user of the **WP200** requires continued operation during power mains interruptions; it is recommended that **WP200** be powered from a separate power supply (UPS, etc.).
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical public low-voltage power supply network that supplies buildings used for domestic purposes, commercial or hospital, clinic environment.
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

Table 4 - from IEC 60601-1-2:2007

Guidance and manufacturer's declaration – electromagnetic immunity – WP200

The **WP 200** is intended for use in the electromagnetic environment specified below; The customer or the user of the **WP200** should assure that it is used in such an environment.

Immunity test	**IEC 60601-1-2** **Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 k Hz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the **WP200**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter . **Recommended separation distance** $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P}$ 80 M Hz t o 800 MHz $d = 2.3\sqrt{P}$ 800 MHz t o 2,5 GHz where P i s the maximum output power rating of the transmitter in watts (W)according to the transmitter manufacturer and d i s the recommended separation Distance in meters (m). Field strengths from fixed R F transmitters, as determined by an electromagnetic site survey ,[a] should be less than the compliance level in each frequency range .[d] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations .Electromagnetic propagation is affected by absorption And reflection from structures objects and people.

a
Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **WP200** is used exceeds the applicable RF compliance level above, the **WP200** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **WP200**.

b
Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances

The WP200 is intended for use in an electromagnetic environment in which radiated radiofrequency disturbances are controlled.
The user and/or installer of the unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile radiofrequency communications equipment (emitters) and the WP200, according to the maximum output power of the equipment, as recommended in the table below.

Table 6 - from IEC 60601-1-2:2007

Recommended separation distances between portable and mobile RF communications equipment and the WP200

Rated maximum output power of transmitter Watts [W]	Separation distance according to frequency of transmitter (in meters) Meters [m]		
	150kHz to 80MHz $d = 1.17\sqrt{P}$	80MHz to 800MHz $d = 1.17\sqrt{P}$	800MHz to 2.5GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.73
1	1.17	1.17	2.3
10	3.7	3.7	7.3
100	11.7	11.7	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

APPENDIX G: SPO_2 ACCURACY IN THE WP200

The WatchPAT™200 device uses Nonin module for SPO_2 measurement.
Nonin module measurement wavelengths and output power parameters:

- Red: 660 nanometers @ 0.8 mW maximum average
- Infrared (using NONIN PureLight® Sensor): 910 nanometers @ 1.2 mW maximum average.

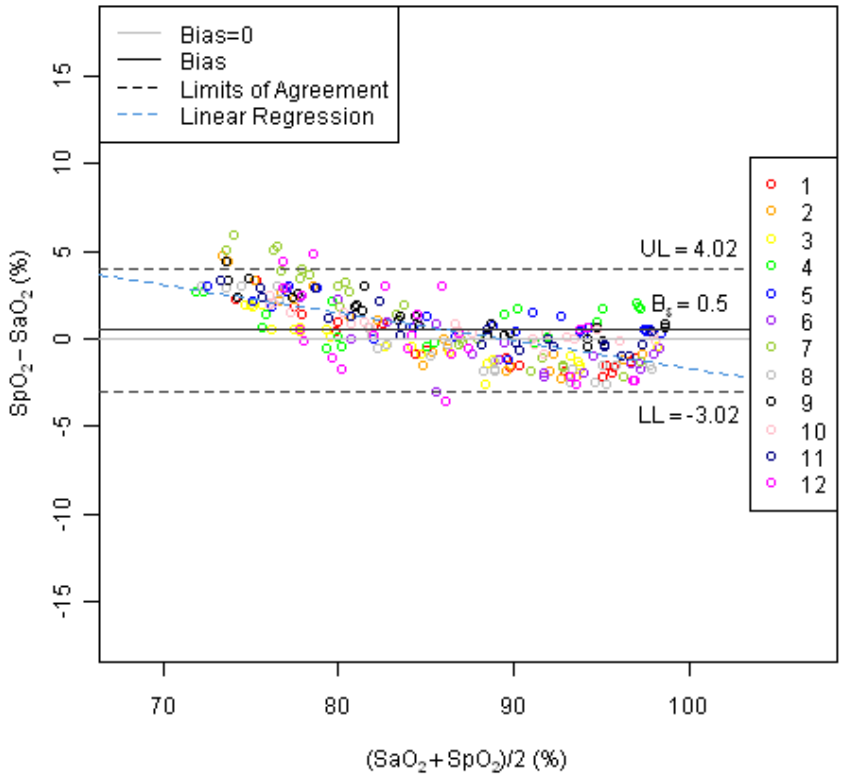
This appendix includes information regarding the accuracy of these measurements, according to module manufacturer information (*).

1. Overall, the ARMS is estimated to be 1.85 across the range of 70 to 100 percent saturation, and with 95% confidence ranges from 1.59 to 2.3.

2. The next table shows A_{RMS} values measured using the Nonin module:

Range of SpO_2	**A_{RMS}**	**95% confidence level**
70-80%	2.79	(2.296, 3.450)
80-90%	1.23	(1.034, 1.470)
90-100%	1.33	(1.021, 1.567)

3. The next figure shows the A Bland-Altman plot of the Bias (SpO_2 –SaO_2) versus the Mean (½SaO_2+½SpO_2).
   Solid gray lines represent the mean bias. Dashed gray lines represent the 95% limits of agreement.



*Source of data:

Title:	Verification of SpO2 Accuracy Performance of the OEM III Pulse Oximeter Module (rev 14) in Non-Motion Conditions)
Version:	B
Date:	2010-01-27
Report ID:	QATR5334 Abbreviated
Clinical Investigator(s):	Hypoxia Research Laboratory Department of Anesthesiology, M1427 UCSF San Francisco, CA 94143-0542
Sponsor:	Nonin Medical 13700 1st Avenue North Plymouth, MN 55441-5443
Device(s):	Non-Motion: OEMIII-8000J
Study Date(s):	July 19, 2006 through July 20, 2006

APPENDIX H: TRAINING RESOURCES

WatchPAT™ device training materials can be found and downloaded from:
www.itamar-medical.com/training
These files can also be viewed through any smartphone running QR code reader or optical scanner application, by scanning the code next to each resource.
The following resources can be found on this page:

Technician Training Presentation	
Step-by-Step Card – English	
zzzPAT User Manual	
WP200 Patient Video	
zzzPAT Manual Editing of Sleep Scoring	

APPENDIX I: SPARE PARTS LIST

The following items can be ordered and purchased individually:

- PAT probe (a box of 12 PAT probes)
- PAT probe connection cable
- Wrist Strap
- Snore and Body Position sensor
- Adhesive set for Snore and Body Position sensor
- Pulse oximeter sensor
- Adhesive set for Pulse oximeter sensor
- Cable for Tamper-Proof Bracelet
- Tamper-Proof Bracelet (a box of 24 bracelets)
- AC adapter
- USB cable
- Rechargeable Lithium Ion Battery
- Step-by-Step Reference Guide WP200 + Itamar SBP
- Quick Reference Cards WP200
- Carrying case